Update on NCTN Trial Funding for New NCTN Grant Period Beginning March 1, 2019

NIH
NATIONAL CANCER INSTITUTE

April 24, 2019
New NCTN Program Funding
Increase in Per-Case Reimbursement for Participating NCTN Sites

• Funding increases in per-case reimbursement for NCTN sites are set for treatment intervention, screening, and imaging accrual
  • Federal NCORP funding levels have been set for the NCORP grant cycle that runs through August 2019. Based on the NCORP funding plan for the next grant cycle, funding levels may be updated in Fall 2019.
  • Funding increases for treatment intervention are graduated based on general trial category – split into 3 major categories
    • Non-IND studies
    • Non-CTEP IND studies
    • CTEP IND studies
• Biospecimen collections remain variable
## New NCTN Program Funding
### Principal Changes in Per-Case Reimbursement to Sites: Funding Sheets

<table>
<thead>
<tr>
<th>Accrual Type</th>
<th>New Standard Site Rate</th>
<th>New High Performance Site (LAPS) Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening on Study</td>
<td>$600 (Variable)</td>
<td>$600 (Variable)</td>
</tr>
<tr>
<td>Treatment Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-IND study</td>
<td>$2,700</td>
<td>$4,300</td>
</tr>
<tr>
<td>IND study (Non-CTEP)</td>
<td>$3,000</td>
<td>$4,600</td>
</tr>
<tr>
<td>IND study (CTEP)</td>
<td>$3,600</td>
<td>$5,200</td>
</tr>
<tr>
<td>Imaging (base accrual)</td>
<td>$1,200</td>
<td>$1,200</td>
</tr>
<tr>
<td>Biospecimen Collections</td>
<td>Variable</td>
<td>Variable</td>
</tr>
<tr>
<td></td>
<td>$500/pt/trial</td>
<td>$500/pt/trial</td>
</tr>
</tbody>
</table>
New NCTN Per-Case Funding – Qualifications (1)

- The new levels have been applied to new NCTN trials with funding sheets prepared on or after March 1, 2019
- Trials with funding sheets prepared/activated prior to March 1, 2019, that are enrolling patients will have funding levels increased with the following caveats:
  - Trials with “additional” capitation amounts already in place (e.g., due to increased industry or other federal funding) will not have their NCTN funding levels increased if the total level of funding for the intervention already exceeds the new NCTN rates
  - If a trial has “additional” capitation but the amount does not exceed the new NCTN funding levels, the trial will receive new NCTN funding to bring its per-case amount up to the new NCTN levels
New NCTN Per-Case Funding – Qualifications (2)

• Some funding sheets prepared/activated prior to March 1, 2019 that are enrolling patients and newly activated studies after March 1st, may have unique funding levels for the following caveats:
  • The few trials activated before March 1st that were not primarily funded by the NCTN (e.g., a DOD trial with NCTN collaboration) or a trial that does not have a traditional treatment intervention may not receive new level NCTN funding. This will continue in the new NCTN grant funding program after March 1st, 2019.
  • Trials with observational cohorts/standard of care that are not part of a study’s randomization may be set to receive lower per-case reimbursement rates.
Example of Non-IND Trial Funding with Screening Step

**PROTOCOL S1802**

Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer

*Study Activation Date: 09/17/2018*

**Trial Type: Non-IND**

<table>
<thead>
<tr>
<th>Funding Source and Study Component</th>
<th>Collect Type</th>
<th>Study Specific Notes</th>
<th>Enter Date in Open? (c)</th>
<th>NCTN Funding per Patient (a) Std/HP LAPS</th>
<th>NCORP Funding per Patient (b) Std/HP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Screening for Intervention Step 1 Registration – SEE NOTES</td>
<td>Mandatory</td>
<td>1</td>
<td>No</td>
<td>$600</td>
<td>$500</td>
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<tr>
<td>Federal Base Intervention – Standard / High Performance LAPS &amp; NCORP</td>
<td>Mandatory</td>
<td>No</td>
<td></td>
<td>$2,100/$3,700</td>
<td>$2,000/$3,500</td>
</tr>
<tr>
<td>Federal Biospecimen – Tissue (Step 1 Registration)</td>
<td>Mandatory Request</td>
<td>2</td>
<td>Yes</td>
<td>$100</td>
<td>$100</td>
</tr>
<tr>
<td>Federal Biospecimen – Tissue (Step 2 Randomization)</td>
<td>Mandatory Request</td>
<td>2</td>
<td>Yes</td>
<td>$100</td>
<td>$100</td>
</tr>
</tbody>
</table>
Funding Sheet Updates

- All updated funding sheets are posted on the CTSU website for each NCTN protocol under the tab: Funding Information (scroll to bottom)
- For any questions related to the Funding Information, please contact the Lead NCTN Group contact listed on the funding sheet.
- For CTSU-related questions, please contact the CTSU Help Desk at:
  - ctsucontact@westat.com
Questions?

- **ORP Open Forum**
  - Table: Site Payments & National Coverage Analysis
  - Thursday, April 25th (tomorrow); 12:30 – 2:00pm
  - Pacific MNO (Pacific Concourse Level)

- **Federal Site Payment Transition – Office Hours**
  - Thursday, April 25th (tomorrow); 5:00 – 6:00pm
  - Pacific A (Pacific Concourse Level)

- **SWOG Contact Information**
  - Pat Mize: mizep@ohsu.edu
  - Kyle Theige: theige@ohsu.edu